§112.11

Subpart B—General Requirements

\$112.11 What general requirements apply to persons who are subject to this part?

You must take appropriate measures to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act on account of such hazards.

§ 112.12 Are there any alternatives to the requirements established in this nart?

- (a) You may establish alternatives to certain specific requirements of subpart E of this part, as specified in §112.49, provided that you satisfy the requirements of paragraphs (b) and (c) of this section.
- (b) You may establish and use an alternative to any of the requirements specified in paragraph (a) of this section, provided you have adequate scientific data or information to support a conclusion that the alternative would provide the same level of public health protection as the applicable requirement established in this part, and would not increase the likelihood that your covered produce will be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act, in light of your covered produce, practices, and conditions.
- (c) Scientific data and information used to support an alternative to a requirement specified in paragraph (a) of this section may be developed by you, available in the scientific literature, or available to you through a third party. You must establish and maintain documentation of the scientific data and information on which you rely in accordance with the requirements of subpart O of this part. You are not required to notify or seek prior approval from FDA regarding your decision to establish or use an alternative under this section.

Subpart C—Personnel Qualifications and Training

§112.21 What requirements apply regarding qualifications and training for personnel who handle (contact) covered produce or food contact surfaces?

All of the following requirements apply regarding qualifications and training for personnel who handle (contact) covered produce or food contact surfaces:

- (a) All personnel (including temporary, part time, seasonal, and contracted personnel) who handle covered produce or food contact surfaces, or who are engaged in the supervision thereof, must receive adequate training, as appropriate to the person's duties, upon hiring, and periodically thereafter, at least once annually.
- (b) All personnel (including temporary, part time, seasonal, and contracted personnel) who handle covered produce or food contact surfaces, or who are engaged in the supervision thereof, must have a combination of education, training, and experience necessary to perform the person's assigned duties in a manner that ensures compliance with this part.
- (c) Training must be conducted in a manner that is easily understood by personnel being trained.
- (d) Training must be repeated as necessary and appropriate in light of observations or information indicating that personnel are not meeting standards established by FDA in subparts C through O of this part.

§112.22 What minimum requirements apply for training personnel who conduct a covered activity?

- (a) At a minimum, all personnel who handle (contact) covered produce during covered activities or supervise the conduct of such activities must receive training that includes all of the following:
- (1) Principles of food hygiene and food safety:
- (2) The importance of health and personal hygiene for all personnel and visitors, including recognizing symptoms of a health condition that is reasonably likely to result in contamination of covered produce or food contact